IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, LLC, FRESENIUS KABI USA, INC. and FRESENIUS KABI ONCOLOGY LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pharmacyclics LLC ("Pharmacyclics") and Janssen Biotech, Inc. ("Janssen"), (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; and Fresenius Kabi Oncology Limited (collectively, "Fresenius Kabi"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Fresenius Kabi's recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 210896 ("Fresenius Kabi's ANDA"). Fresenius Kabi seeks approval to market a generic version of Plaintiffs' highly successful pharmaceutical product IMBRUVICA®, prior to the expiration of United States Patent Nos. 8,008,309 ("the '309 Patent"); 7,514,444 ("the '444 Patent"); 8,697,711 ("the '711 Patent"); 8,735,403 ("the '403 Patent"); 8,957,079 ("the '079 Patent"); 9,181,257 ("the '257 Patent"); 8,754,091 ("the '091 Patent"); 8,497,277 ("the '277 Patent"); 8,952,015 ("the '015 Patent"); 8,476,284 ("the '284 Patent"); 8,754,090 ("the '090

Patent"); 9,296,753 ("the '753 Patent"); 9,725,455 ("the '455 Patent"); 9,540,382 ("the '382 Patent"); and 9,713,617 ("the '617 Patent").

IMBRUVICA®

2. IMBRUVICA® (ibrutinib) is a ground-breaking drug which covalently binds to a protein called Bruton's tyrosine kinase ("BTK"), thereby irreversibly inhibiting BTK's activity.

3. BTK is a key signaling molecule in the pathway that leads to B-cell growth and maturation following activation of the B-cell receptor. Abnormalities in the B-cell receptor signaling pathway can lead to uncontrolled cell growth and cause cancers of the blood and bone marrow. IMBRUVICA® is the first FDA-approved BTK inhibitor.

4. Pharmacyclics invested hundreds of millions of dollars in the development of IMBRUVICA®. Pharmacyclics partnered with Janssen to bring this revolutionary drug to patients across the United States and throughout the world. Janssen, recognizing the potential of the compound, invested hundreds of millions of dollars in the clinical development and commercialization of IMBRUVICA®.

5. Initial clinical trials using IMBRUVICA® to treat mantle cell lymphoma ("MCL") showed that patients taking IMBRUVICA® had an observed response rate of 68%. These results led FDA to grant accelerated approval to IMBRUVICA® for the treatment of MCL in patients who had received at least one prior therapy through the new Breakthrough Therapy Designation pathway, a process that allows the FDA to grant priority review to drug candidates if preliminary clinical trials indicate that the therapy may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. IMBRUVICA® was one of the first drugs ever to receive FDA approval via the Breakthrough Therapy Designation.

6. IMBRUVICA® has received three additional Breakthrough Therapy Designations for three additional indications: Waldenström's macroglobulinemia; chronic lymphocytic

leukemia ("CLL") or small lymphocytic lymphoma ("SLL") with a deletion of the short arm of chromosome 17 (del 17p); and chronic graft-versus-host-disease ("cGVHD"). IMBRUVICA® is also indicated for the treatment of marginal zone lymphoma ("MZL") in patients who require systemic therapy and have received at least one prior anti-CD20-based therapy and the treatment of CLL/SLL. For MZL and cGVHD, IMBRUVICA® represents the first FDA approved treatment specifically for patients with these disorders.

7. IMBRUVICA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with approximately 130 ongoing clinical trials. There are approximately 30 ongoing company-sponsored trials, 14 of which are in Phase 3, and approximately 100 investigator-sponsored trials and external collaborations that are active around the world.

8. IMBRUVICA® has gained widespread acceptance in the medical community with more than 70,000 patients around the world having been treated with IMBRUVICA®. In 2015, IMBRUVICA® was awarded the prestigious Prix Galien Award for Best Pharmaceutical Agent. The Prix Galien Award is considered the biomedical industry's highest accolade.

9. The '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '382, and '617 Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for IMBRUVICA®.

THE PARTIES

10. Plaintiff Pharmacyclics LLC is a limited liability company organized and existing under the laws of the Delaware with its principal place of business at 999 East Arques Avenue, Sunnyvale, California 94085. Pharmacyclics is a wholly owned subsidiary of AbbVie Inc., a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. Pharmacyclics is the assignee and owner of the '309, '444, '711,

'403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '382, and '617 Patents. Pharmacyclics holds New Drug Application ("NDA") No. 205552 for IMBRUVICA®.

11. Plaintiff Janssen Biotech, Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen is a wholly owned subsidiary of Johnson & Johnson. Janssen is the exclusive licensee of the Orange Book patents for IMBRUVICA®. Janssen is engaged in the clinical development and commercialization of IMBRUVICA® and shares in the proceeds from U.S. sales of IMBRUVICA®.

12. On information and belief, Defendant Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. On information and belief, Fresenius Kabi USA, LLC is a wholly-owned subsidiary of Fresenius Kabi USA, Inc.

13. On information and belief, Defendant Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

14. On information and belief, Defendant Fresenius Kabi Oncology Limited is a corporation organized and existing under the laws of India, with a principal place of business at D-35, Industrial Area, Kalyani, District Nadia, West Bangal - 741 235, India.

15. On further information and belief, Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; and Fresenius Kabi Oncology Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, the Fresenius Kabi Defendants are agents of one another and/or operate in concert as integrated parts of the same business group.

16. On information and belief, Fresenius Kabi caused ANDA No. 210896 to be submitted to FDA and seeks FDA approval of ANDA No. 210896.

17. On information and belief, Fresenius Kabi Oncology Limited holds Drug Master File ("DMF") No. 31199 for ibrutinib.

18. On information and belief, Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; and Fresenius Kabi Oncology Limited acted collaboratively in the preparation and submission of ANDA No. 210896 and DMF No. 31199 and continue to act collaboratively in pursuing FDA approval of ANDA No. 210896 and seeking to market generic ibrutinib capsules.

19. On information and belief, Fresenius Kabi intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Fresenius Kabi's ANDA ("Fresenius Kabi's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Fresenius Kabi's ANDA.

20. On information and belief, Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; and Fresenius Kabi Oncology Limited rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; and Fresenius Kabi Oncology Limited intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Fresenius Kabi's ANDA Product, in the event FDA approves Fresenius Kabi's ANDA.

JURISDICTION AND VENUE

21. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

23. This Court has personal jurisdiction over Fresenius Kabi because Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware and Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of Delaware. On information and belief, Fresenius Kabi USA, LLC is registered to do business as a domestic limited liability company in Delaware (File Number 4373141). On information and belief, Fresenius Kabi USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 4373132).

24. Additionally, this Court has personal jurisdiction over Fresenius Kabi because, on information and belief, Fresenius Kabi, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Fresenius Kabi's ANDA Product in the State of Delaware upon approval of ANDA No. 210896.

25. On information and belief, Fresenius Kabi is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Fresenius Kabi manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

26. On information and belief, Fresenius Kabi is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

27. Fresenius Kabi has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm

and injury to Plaintiffs, which manufacture and/or market IMBRUVICA® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter dated December 20, 2017 sent by Fresenius Kabi USA, LLC to, *inter alia*, Pharmacyclics and Janssen pursuant to 21 U.S.C. § 355(j)(2)(B) ("Notice Letter"), Fresenius Kabi prepared and filed its ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

28. On information and belief, Fresenius Kabi plans to sell its ANDA Product in the State of Delaware, list its ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

29. On information and belief, Fresenius Kabi knows and intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of IMBRUVICA®, causing injury to Plaintiffs. Fresenius Kabi intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

30. Fresenius Kabi USA, LLC regularly invokes the jurisdiction of the courts of this judicial district by filing patent infringement actions concerning FDA-approved drug products in this judicial district. *See, e.g.*, *Fresenius Kabi USA, LLC et al. v. Sagent Pharmaceuticals, Inc.*, C.A. No. 17-011-LPS, D.I. 1 (D. Del. Jan. 4, 2017); *Fresenius Kabi USA, LLC v. B. Braun Medical Inc.*, C.A. No. 16-250-RGA, D.1. 1 (D. Del. Apr. 11, 2016); *Fresenius Kabi USA, LLC v. Maia Pharmaceuticals, Inc.*, C.A. No. 16-237-GMS (D. Del. Apr. 7, 2016). Fresenius Kabi USA, LLC and Fresenius Kabi USA, Inc. also have not contested personal jurisdiction or venue in patent litigation concerning FDA-approved drug products in this judicial district. *See, e.g.*,

Onyx Therapeutics, Inc. v. Fresenius Kabi USA, LLC, C.A. No. 16-1012-LPS, D.I. 19 (D. Del. Jan. 6, 2017); *Teva Pharmaceuticals International GmbH v. Fresenius Kabi USA, LLC*, C.A. No. 17-1201-GMS, D.I. 10 (D. Del. Sept. 15, 2017); *Astellas Pharma Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 15-080-LPS, D.I. 7 (D. Del. Feb. 13, 2015).

31. This Court has personal jurisdiction over Fresenius Kabi Oncology Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Fresenius Kabi Oncology Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Fresenius Kabi Oncology Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Fresenius Kabi's ANDA, preparing and submitting DMF No. 31199 to FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Fresenius Kabi Oncology Limited satisfies due process.

32. Venue is proper in this district for Fresenius Kabi USA, LLC pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware.

33. Venue is proper in this district for Fresenius Kabi USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

34. Venue is proper in this district for Fresenius Kabi Oncology Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Fresenius Kabi Oncology Limited is a corporation organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

THE ASSERTED PATENTS

35. The ’309 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on August 30, 2011. A true and correct copy of the ’309 Patent is attached hereto as Exhibit A.

36. The ’444 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on April 7, 2009. A true and correct copy of the ’444 Patent is attached hereto as Exhibit B.

37. The ’711 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on April 15, 2014. A true and correct copy of the ’711 Patent is attached hereto as Exhibit C.

38. The ’403 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on May 27, 2014. A true and correct copy of the ’403 Patent is attached hereto as Exhibit D.

39. The ’079 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on February 17, 2015. A true and correct copy of the ’079 Patent is attached hereto as Exhibit E.

40. The ’257 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on November 10, 2015. A true and correct copy of the ’257 Patent is attached hereto as Exhibit F.

41. The ’091 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on June 17, 2014. A true and correct copy of the ’091 Patent is attached hereto as Exhibit G.

42. The ’277 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on July 30, 2013. A true and correct copy of the ’277 Patent is attached hereto as Exhibit H.

43. The ’015 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on February 10, 2015. A true and correct copy of the ’015 Patent is attached hereto as Exhibit I.

44. The ’284 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on July 2, 2013. A true and correct copy of the ’284 Patent is attached hereto as Exhibit J.

45. The ’090 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on June 17, 2014. A true and correct copy of the ’090 Patent is attached hereto as Exhibit K.

46. The ’753 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on March 29, 2016. A true and correct copy of the ’753 Patent is attached hereto as Exhibit L.

47. The ’455 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on August 8, 2017. A true and correct copy of the ’455 Patent is attached hereto as Exhibit M.

48. The ’382 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on January 10, 2017. A true and correct copy of the ’382 Patent is attached hereto as Exhibit N.

49. The ’617 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on July 25, 2017. A true and correct copy of the ’617 Patent is attached hereto as Exhibit O.

FRESENIUS KABI’S ANDA NO. 210896

50. On information and belief, Fresenius Kabi has submitted ANDA No. 210896 to FDA, or caused ANDA No. 210896 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents.

51. On information and belief, FDA has not approved Fresenius Kabi’s ANDA.

52. Fresenius Kabi USA, LLC sent Pharmacyclics and Janssen a Notice Letter dated December 20, 2017. The Fresenius Kabi Notice Letter represented that Fresenius Kabi USA, LLC had submitted to FDA ANDA No. 210896 and a purported Paragraph IV certification for, *inter alia*, the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents.

53. According to applicable regulations, Notice Letters such as Fresenius Kabi’s must contain a detailed statement of the factual and legal basis for the applicant’s opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing “for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” *See* 21 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

54. For at least one claim of each of the ’309, ’444, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents, Fresenius Kabi’s Notice Letter failed to allege

that its ANDA Product or the proposed administration of that Product would not meet the limitations of that claim.

55. On information and belief, if FDA approves Fresenius Kabi's ANDA, Fresenius Kabi will manufacture, offer for sale, or sell its ANDA Product, within the United States, including within the State of Delaware, or will import its ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Fresenius Kabi's ANDA Product will directly infringe the '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '382, and '617 Patents and Fresenius Kabi will actively induce and/or contribute to their infringement.

56. This action is being brought within forty-five days of Plaintiffs' receipt of Fresenius Kabi's Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE '309 PATENT BY FRESENIUS KABI

57. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–56 as if fully set forth herein.

58. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

59. Plaintiffs own all rights, title, and interest in and to the '309 Patent.

60. Fresenius Kabi's ANDA Product infringes one or more claims of the '309 Patent.

61. Fresenius Kabi did not contest infringement of at least claims 1–7, 10, and 14 of the '309 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or

legal basis to contest infringement of the claims of the '309 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

62. Fresenius Kabi has infringed one or more claims of the '309 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '309 Patent.

63. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '309 Patent would infringe one or more claims of the '309 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '309 Patent under 35 U.S.C. § 271 (b) and/or (c).

64. Fresenius Kabi had actual and constructive notice of the '309 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '309 Patent would constitute an act of infringement of the '309 Patent.

65. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '309 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '309 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

66. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '309 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '444 PATENT BY FRESENIUS KABI

67. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–66 as if fully set forth herein.

68. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

69. Plaintiffs own all rights, title, and interest in and to the '444 Patent.

70. Fresenius Kabi's ANDA Product infringes one or more claims of the '444 Patent.

71. Fresenius Kabi did not contest infringement of claims 1–8 of the '444 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '444 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

72. Fresenius Kabi has infringed one or more claims of the '444 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '444 Patent.

73. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '444 Patent would infringe

one or more claims of the ’444 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the ’444 Patent under 35 U.S.C. § 271 (b) and/or (c).

74. Fresenius Kabi had actual and constructive notice of the ’444 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the ’444 Patent would constitute an act of infringement of the ’444 Patent.

75. Fresenius Kabi filed its ANDA without adequate justification for asserting that the ’444 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi’s conduct in certifying invalidity with respect to the ’444 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

76. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’444 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE ’711 PATENT BY FRESENIUS KABI

77. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–76 as if fully set forth herein.

78. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

79. Plaintiffs own all rights, title, and interest in and to the '711 Patent.

80. Fresenius Kabi's ANDA Product infringes one or more claims of the '711 Patent.

81. Fresenius Kabi has infringed one or more claims of the '711 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '711 Patent.

82. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '711 Patent would infringe one or more claims of the '711 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '711 Patent under 35 U.S.C. § 271 (b) and/or (c).

83. Fresenius Kabi had actual and constructive notice of the '711 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '711 Patent would constitute an act of infringement of the '711 Patent.

84. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '711 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '711 Patent renders this case "exceptional"

as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

85. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '711 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE '403 PATENT BY FRESENIUS KABI

86. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–85 as if fully set forth herein.

87. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

88. Plaintiffs own all rights, title, and interest in and to the '403 Patent.

89. Fresenius Kabi's ANDA Product infringes one or more claims of the '403 Patent.

90. Fresenius Kabi did not contest infringement of claims 1–13 of the '403 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '403 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

91. Fresenius Kabi has infringed one or more claims of the '403 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '403 Patent.

92. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '403 Patent would infringe one or more claims of the '403 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '403 Patent under 35 U.S.C. § 271 (b) and/or (c).

93. Fresenius Kabi had actual and constructive notice of the '403 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '403 Patent would constitute an act of infringement of the '403 Patent.

94. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '403 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '403 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

95. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '403 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V
INFRINGEMENT OF THE '079 PATENT BY FRESENIUS KABI

96. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–95 as if fully set forth herein.

97. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

98. Plaintiffs own all rights, title, and interest in and to the '079 Patent.

99. Fresenius Kabi's ANDA Product infringes one or more claims of the '079 Patent.

100. Fresenius Kabi did not contest infringement of at least claims 1–5, 7, 11, and 12 of the '079 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '079 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

101. Fresenius Kabi has infringed one or more claims of the '079 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '079 Patent.

102. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '079 Patent would infringe one or more claims of the '079 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '079 Patent under 35 U.S.C. § 271 (b) and/or (c).

103. Fresenius Kabi had actual and constructive notice of the '079 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '079 Patent would constitute an act of infringement of the '079 Patent.

104. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '079 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '079 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

105. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '079 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
INFRINGEMENT OF THE '257 PATENT BY FRESENIUS KABI

106. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–105 as if fully set forth herein.

107. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

108. Plaintiffs own all rights, title, and interest in and to the '257 Patent.

109. Fresenius Kabi's ANDA Product infringes one or more claims of the '257 Patent.

110. Fresenius Kabi did not contest infringement of at least claims 1–5, 8–10, and 13 of the '257 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '257 Patent, it was required by

applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

111. Fresenius Kabi has infringed one or more claims of the '257 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '257 Patent.

112. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '257 Patent would infringe one or more claims of the '257 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '257 Patent under 35 U.S.C. § 271 (b) and/or (c).

113. Fresenius Kabi had actual and constructive notice of the '257 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '257 Patent would constitute an act of infringement of the '257 Patent.

114. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '257 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '257 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

115. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '257 Patent.

Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VII
INFRINGEMENT OF THE '091 PATENT BY FRESENIUS KABI

116. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–115 as if fully set forth herein.

117. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

118. Plaintiffs own all rights, title, and interest in and to the '091 Patent.

119. Fresenius Kabi's ANDA Product infringes one or more claims of the '091 Patent.

120. Fresenius Kabi did not contest infringement of claims 1–21 of the '091 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '091 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

121. Fresenius Kabi has infringed one or more claims of the '091 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '091 Patent.

122. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '091 Patent would infringe one or more claims of the '091 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would

induce the infringement of and/or contribute to the infringement of one or more claims of the '091 Patent under 35 U.S.C. § 271 (b) and/or (c).

123. Fresenius Kabi had actual and constructive notice of the '091 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '091 Patent would constitute an act of infringement of the '091 Patent.

124. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '091 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '091 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

125. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '091 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
INFRINGEMENT OF THE '277 PATENT BY FRESENIUS KABI

126. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–125 as if fully set forth herein.

127. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

128. Plaintiffs own all rights, title, and interest in and to the '277 Patent.

129. Fresenius Kabi's ANDA Product infringes one or more claims of the '277 Patent.

130. Fresenius Kabi has infringed one or more claims of the '277 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '277 Patent.

131. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '277 Patent would infringe one or more claims of the '277 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '277 Patent under 35 U.S.C. § 271 (b) and/or (c).

132. Fresenius Kabi had actual and constructive notice of the '277 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '277 Patent would constitute an act of infringement of the '277 Patent.

133. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '277 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '277 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

134. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '277 Patent.

Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IX
INFRINGEMENT OF THE '015 PATENT BY FRESENIUS KABI

135. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–134 as if fully set forth herein.

136. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

137. Plaintiffs own all rights, title, and interest in and to the '015 Patent.

138. Fresenius Kabi's ANDA Product infringes one or more claims of the '015 Patent.

139. Fresenius Kabi has infringed one or more claims of the '015 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '015 Patent.

140. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '015 Patent would infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '015 Patent under 35 U.S.C. § 271 (b) and/or (c).

141. Fresenius Kabi had actual and constructive notice of the '015 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for

FDA approval prior to the expiration of the ’015 Patent would constitute an act of infringement of the ’015 Patent.

142. Fresenius Kabi filed ANDA without adequate justification for asserting that the ’015 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi’s conduct in certifying invalidity and/or non-infringement with respect to the ’015 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

143. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’015 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
INFRINGEMENT OF THE ’284 PATENT BY FRESENIUS KABI

144. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–143 as if fully set forth herein.

145. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi’s ANDA Product.

146. Plaintiffs own all rights, title, and interest in and to the ’284 Patent.

147. Fresenius Kabi’s ANDA Product infringes one or more claims of the ’284 Patent.

148. Fresenius Kabi has infringed one or more claims of the ’284 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification

and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '284 Patent.

149. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '284 Patent would infringe one or more claims of the '284 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '284 Patent under 35 U.S.C. § 271 (b) and/or (c).

150. Fresenius Kabi had actual and constructive notice of the '284 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '284 Patent would constitute an act of infringement of the '284 Patent.

151. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '284 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '284 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

152. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '284 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XI
INFRINGEMENT OF THE ’090 PATENT BY FRESENIUS KABI

153. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–152 as if fully set forth herein.

154. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi’s ANDA Product.

155. Plaintiffs own all rights, title, and interest in and to the ’090 Patent.

156. Fresenius Kabi’s ANDA Product infringes one or more claims of the ’090 Patent.

157. Fresenius Kabi has infringed one or more claims of the ’090 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’090 Patent.

158. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi’s ANDA Product prior to the expiration of the ’090 Patent would infringe one or more claims of the ’090 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the ’090 Patent under 35 U.S.C. § 271 (b) and/or (c).

159. Fresenius Kabi had actual and constructive notice of the ’090 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the ’090 Patent would constitute an act of infringement of the ’090 Patent.

160. Fresenius Kabi filed its ANDA without adequate justification for asserting that the ’090 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture,

use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '090 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

161. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '090 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
INFRINGEMENT OF THE '753 PATENT BY FRESENIUS KABI

162. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–161 as if fully set forth herein.

163. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

164. Plaintiffs own all rights, title, and interest in and to the '753 Patent.

165. Fresenius Kabi's ANDA Product infringes one or more claims of the '753 Patent.

166. Fresenius Kabi did not contest infringement of claims 1–18 of '753 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '753 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

167. Fresenius Kabi has infringed one or more claims of the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification

and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '753 Patent.

168. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '753 Patent would infringe one or more claims of the '753 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '753 Patent under 35 U.S.C. § 271 (b) and/or (c).

169. Fresenius Kabi had actual and constructive notice of the '753 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '753 Patent would constitute an act of infringement of the '753 Patent.

170. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '753 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity with respect to the '753 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

171. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '753 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XIII
INFRINGEMENT OF THE ’455 PATENT BY FRESENIUS KABI

172. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–171 as if fully set forth herein.

173. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi’s ANDA Product.

174. Plaintiffs own all rights, title, and interest in and to the ’455 Patent.

175. Fresenius Kabi’s ANDA Product infringes one or more claims of the ’455 Patent.

176. Fresenius Kabi did not contest infringement of claims 1–13 of the ’455 Patent in Fresenius Kabi USA, LLC’s Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the ’455 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

177. Fresenius Kabi has infringed one or more claims of the ’455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’455 Patent.

178. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi’s ANDA Product prior to the expiration of the ’455 Patent would infringe one or more claims of the ’455 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the ’455 Patent under 35 U.S.C. § 271 (b) and/or (c).

179. Fresenius Kabi had actual and constructive notice of the ’455 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for

FDA approval prior to the expiration of the ’455 Patent would constitute an act of infringement of the ’455 Patent.

180. Fresenius Kabi filed its ANDA without adequate justification for asserting that the ’455 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi’s conduct in certifying invalidity with respect to the ’455 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

181. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’455 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XIV
INFRINGEMENT OF THE ’382 PATENT BY FRESENIUS KABI

182. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–181 as if fully set forth herein.

183. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi’s ANDA Product.

184. Plaintiffs own all rights, title, and interest in and to the ’382 Patent.

185. Fresenius Kabi’s ANDA Product infringes one or more claims of the ’382 Patent.

186. Fresenius Kabi has infringed one or more claims of the ’382 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification

and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '382 Patent.

187. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '382 Patent would infringe one or more claims of the '382 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '382 Patent under 35 U.S.C. § 271 (b) and/or (c).

188. Fresenius Kabi had actual and constructive notice of the '382 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '382 Patent would constitute an act of infringement of the '382 Patent.

189. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '382 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '382 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

190. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '382 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XV
INFRINGEMENT OF THE '617 PATENT BY FRESENIUS KABI

191. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–190 as if fully set forth herein.

192. On information and belief, Fresenius Kabi submitted or caused the submission of ANDA No. 210896 to FDA, and thereby seeks FDA approval of Fresenius Kabi's ANDA Product.

193. Plaintiffs own all rights, title, and interest in and to the '617 Patent.

194. Fresenius Kabi's ANDA Product infringes one or more claims of the '617 Patent.

195. Fresenius Kabi did not contest infringement of at least claims 1–9, 11, 15–16, 19–35, or 38–39 of the '617 Patent in Fresenius Kabi USA, LLC's Notice Letter. If Fresenius Kabi had a factual or legal basis to contest infringement of the claims of the '617 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

196. Fresenius Kabi has infringed one or more claims of the '617 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210896 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '617 Patent.

197. On information and belief, the importation, manufacture, sale, offer for sale, or use of Fresenius Kabi's ANDA Product prior to the expiration of the '617 Patent would infringe one or more claims of the '617 Patent under 35 U.S.C. § 271(a), and/or Fresenius Kabi would induce the infringement of and/or contribute to the infringement of one or more claims of the '617 Patent under 35 U.S.C. § 271 (b) and/or (c).

198. Fresenius Kabi had actual and constructive notice of the '617 Patent prior to filing ANDA No. 210896, and was aware that the filing of ANDA No. 210896 with the request for FDA approval prior to the expiration of the '617 Patent would constitute an act of infringement of the '617 Patent.

199. Fresenius Kabi filed its ANDA without adequate justification for asserting that the '617 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Fresenius Kabi's conduct in certifying invalidity and/or non-infringement with respect to the '617 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

200. Plaintiffs will be irreparably harmed if Fresenius Kabi is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '617 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Fresenius Kabi, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Fresenius Kabi has infringed the '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '382, and '617 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Fresenius Kabi's ANDA shall be no earlier than the last expiration date of any of the '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '382, or '617 Patents, or any later expiration of exclusivity for any of the '309, '444, '711, '403,

’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, or ’617 Patents, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Fresenius Kabi, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Fresenius Kabi or on its behalf from commercially manufacturing, using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Fresenius Kabi’s ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, and ’617 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Fresenius Kabi, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Fresenius Kabi’s ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Fresenius Kabi engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’382, or ’617 Patents, or induces or contributes to

such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(G) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Christopher N. Sipes
Erica N. Andersen
Brianne Bharkhda
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Attorneys for Pharmacyclics LLC

Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt
Lachlan Campbell-Verduyn
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Janssen Biotech, Inc.

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